

LABEL IN PART: (Drum) "S.F. 5073 Lot #4326 T Harmen Tablets Each tablet contains: * * * Ferrous Gluconate 100 mg. * * * Po. Ext. Passion Flower 100 mg. Po. Damiana 2 mg. Po. Nux Vomica 2 mg. * * * As a Hematinic and Bitter Tonic For Use in Iron Deficiency (Dietary) Anemias * * * Distributed by Manhattan Drug, Brooklyn 3, N.Y." and (btl.) "Sanapac's Red Rooster Pills 50 * * * Stimulant and Tonic A Dietary Supplement * * * Distributor The Sanapac Company, Wyoming, Penna. Formula * * * For Men and Women Only."

RESULTS OF INVESTIGATION: The bottles described above were repacked by the dealer from bulk stock as described above.

LIBELED: 12-1-61, M. Dist. Pa.

CHARGE: 402(a)(2)(C)—when shipped and while held for sale, the article contained food additives, namely, passion flower extract, damiana, and nux vomica, which were unsafe within the meaning of 409, since they and their use or intended use were not in conformity with a regulation or exemption in effect pursuant to 409.

The article was alleged also to be misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6953.

DISPOSITION: 1-9-62. Default—destruction.

28399. Controcal. (F.D.C. No. 45721. S. No. 19-840 R.)

QUANTITY: 6,158 cases, 24 5-oz. cans each, at Detroit, Mich., in possession of Milk Proteins, Inc.

SHIPPED: Between 11-11-60 and 2-3-61, from Barrington, Ill.

LABEL IN PART: (Can) "Controcal Controls Calories Complete Balanced Concentrated Food For Weight Control Formula #2—to be mixed with skim milk nutritious * * * and it tastes good * * * Controcal dietary for weight control * * * A complete balanced food—high grade milk protein, vitamins and minerals * * * controls calorie intake while supplying adequate nutrition and appetite satisfaction. Weight loss is achieved comfortably and pleasantly by the low calorie intake. * * * Milk Proteins Inc. Detroit 16, Michigan * * * Ingredients: * * * When the contents of this can (5-oz.) are added to 1 quart of skim milk, the following nutrients are supplied: Calories 900; Protein, gm. 72; Fat, gm. 21; Carbohydrate, gm. 112; Minerals gm. 14.5; Vitamin A, units 5000; * * * Vitamin C. mg. 100; Thiamin, mg. 2; Riboflavin, mg. 3; * * * Calcium, gm. 3.9; Phosphorus, gm. 2.9; * * * Minimum Daily Requirements (adults)."

ACCOMPANYING LABELING: Folders entitled "Controcal Promotion Kit."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 69 percent of the declared amount of phosphorus and 72 percent of the declared amount of calcium.

The article was manufactured by Milk Proteins, Inc., and sent to Barrington, Ill., for packaging. The accompanying labeling was printed at Omaha, Nebr., on order of Milk Proteins, Inc.

LIBELED: 4-19-61, E. Dist. Mich.; amended libel 5-1-61.

CHARGE: 403(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was a complete, balanced, concentrated 900-calorie food; that 72 grams of protein, 5,000 units of vitamin A, 100 milligrams of vitamin C, 2 milligrams of thiamin, 3 milligrams of riboflavin, 3.9 grams of calcium, and 2.9 grams of phosphorus were the minimum

daily adult requirement for those nutrients; that the article "controls calories" supplied adequate nutrition and satisfied the appetite; that the body's nutritive needs were fully met through the use of the article; that the "body tissues, muscles, blood, nails, skin, hair * * * are composed of protein"; that the article's "high protein" level maintained blood sugar level, preventing hunger and speeding up the slimming process; that the article was a low-sodium food; and that five ounces of the article added to one quart of whole milk provided 1,200 calories; and the can label contained statements relative to the nutrient content of the article which were misleading since they failed to reveal the material fact that not all of the nutrients in the declared amounts were supplied by the article prior to the addition of one quart of skim milk; and 403(j)—the article purported to be and was represented as a food for special dietary use, and its label failed to bear, as required by regulations, statements of the percent by weight of the artificial sweeteners in the article, that the artificial sweeteners were nonnutritive, and the statements "Contains — saccharin, a nonnutritive artificial sweetner which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin in such food.

The article was also alleged to be misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6925.

DISPOSITION: 2-20-62 and 2-26-62. Default—delivered to a charitable institution.

28400. Vitamin Cheweez tablets. (F.D.C. No. 44735. S. No. 36-651 R.)

QUANTITY: 20,000 tablets in bulk, 156 unlabeled 100-tablet btls. and 38 labeled 100-tablet btls., at Philadelphia, Pa.

SHIPPED: 3-22-60, from Long Island City, N.Y.

LABEL IN PART: (Drum) "25 M Tablets Vitamin Cheweez Tablets Cherry Each tablet contains * * * Vitamin B-12 USP 3 mcg. * * *"; (btl.) "Children's Chewing Vitamin Tablets Cherry Flavored * * * Each tablet contains * * * Vitamin B-12 USP 3 mcg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 74 percent of the declared amount of vitamin B₁₂. The article had been shipped in bulk and had, in part, been repacked and labeled by the dealer.

LIBELED: 7-21-60, E. Dist. Pa.

CHARGE: 402(b)(1)—while held for sale, the valuable constituent of the article, vitamin B₁₂, had been in part omitted or abstracted from the article; and 403(a)—the label statement "Vitamin B-12 USP 3 mcg." was false and misleading.

DISPOSITION: On 8-15-60, Nysco Laboratories, Inc., Long Island City, N.Y., claimed the article and filed an answer denying that the article was adulterated or misbranded. Thereafter the Government served interrogatories upon the claimant which were answered by the claimant on 2-7-61. On 9-14-61, the court granted the claimant's motion for a representative sample of the article. On 11-6-61, the Government filed a motion to compel further and more complete answers to the interrogatories; and on 3-13-62, such motion was granted. Subsequently the claimants filed further answers to the Government's interrogatories. On 9-19-62, the claimant having consented to a decree without admitting any of the issues of law or fact, judgment was entered providing for condemnation and destruction of the article.